

Policies 7.1.6 and 7.1.7 Imminent and Eligible Death Data Definitions

*Organ Procurement Organization
(OPO) Committee*

Richard Pietroski, MS

Distributed for Public Comment September 2012

Proposal Overview

- The OPTN Contractor began collecting patient level data for all imminent and eligible deaths on January 1, 2008 in hopes that OPOs would have better performance modeling and identify missed donor opportunities
- Periodic data review demonstrated large inconsistencies and variations in how OPOs reported data

Proposal Overview

- The Committee has developed a list of organ specific exclusionary criteria and proposed the elimination of MSOF as a criterion.
- These changes will help to eliminate inconsistent reporting and make the data more valuable.

Public Comment

Concerns raised about:

- AST/ALT value for liver donors
- Bilirubin for liver donors
- Increasing age for liver donors from 70 to 75

Public Comments

- Another major concern was the alignment of the proposed changes with CMS regulations.
- The Committee has been attempting to contact CMS for input on how to address the concerns.
- In the meantime, the Committee has proposed that the new definitions be approved but not implemented until coordination with CMS has been completed.

Resolution 16

RESOLVED, that modifications to Policy 7.1.6 (Eligible Death Definition) and Policy 7.1.7 (Imminent Neurological Death), as set forth in Resolution 16, are hereby approved, effective pending approval from CMS, programming, and notice to OPTN membership.

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Policy 2.8

DCD Model Elements

*Organ Procurement Organization
(OPO) Committee*

Richard Pietroski, MS

Distributed for Public Comment March 2012

Background

- In 2009, the OPTN Board of Directors charged the OPO Committee with reviewing DCD policies to determine if they were consistent with current practice.
- The subcommittee spearheading the DCD policy reviewed determined that existing policies were comprehensive but were out of date and should be modified.
- The Committee made specific changes to update the language and terminology such as changing “Model Elements” to “Requirements.”

Proposal Overview

- The proposed changes to the Donation after Cardiac Death (DCD) Model Elements will clarify and update language for the donation and transplantation community.
- The proposal does not change the current level of oversight by the donor hospital to ensure that appropriate practices are following for a patient's end of life care, and that hospital approved practitioners follow hospital palliative care policies and guidelines involving the withdrawal of life sustaining medical treatment/support.

Background

- This proposal was first distributed for public comment during the March 11, 2011 to June 10, 2011 period and received strong support from the regions, committees, and individuals.
- Prior to the November 2011 Board of Directors meeting, several letters were submitted to the OPTN contractor requesting that the public comment period be reopened to allow the requesting organizations to provide comments.

Organizations opposing proposal

- National Catholic Bioethics Center
- National Catholic Partnership on Disability
- Not Dead Yet

Conference call was held on May 22, 2013.
(No response from Not Dead Yet until an email was sent to the Board last week)

Main concerns raised during public comment

- Donor families being approached about organ donation *before* the time at which a decision to withdraw life sustaining measures has been made.
 - Language has been added that specifies that “the timing of a potential DCD donor evaluation and donation discussion shall be coordinated with the OPO and the patient’s healthcare team, in accordance with hospital policy.”

Main concerns raised during public comment

- Failure to provide safeguards for conscious individuals and the omission of any requirement for psychosocial evaluation of a conscious patient who consents to be an organ donor
- Language has been added that specifies that “Conditions involving a potential DCD donor being medically treated/supported in a conscious mental state shall require that the OPO confirms that the healthcare team has assessed the patient’s competency and capacity to make withdrawal/support and other medical decisions.”

Main concerns raised during public comment

- Additional concerns have been addressed by the OPO Committee and can be found on Pages 90-92 in the Board report.
- The OPO Committee agrees that the ethical concerns and safeguards are paramount in the organ donation process. The changes to the model elements are intended to increase those patient protections and safeguards by ensuring that hospitals and OPOs have specific policies and procedures for donation after circulatory death.

Cardiac to Circulatory

The other aspect of this proposal involves redefining “donation after cardiac death” as “donation after circulatory death” in order to accurately reflect the intent of the Uniform Determination of Death Act’s definition of death. All policies with the terms “donation after cardiac death” will be modified for consistency.

Resolution 17

RESOLVED, that modifications to Policy 2.8 (Model Elements for Controlled DCD), Policies 2.7 (Removal of non-renal organs), 3.5.3.3 (Sharing), 3.5.5 (Payback Requirements), 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years), as set forth in Resolution 17, are hereby approved, effective September 1, 2013.

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